

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.

THIS PAGE BLANK (USPTO)

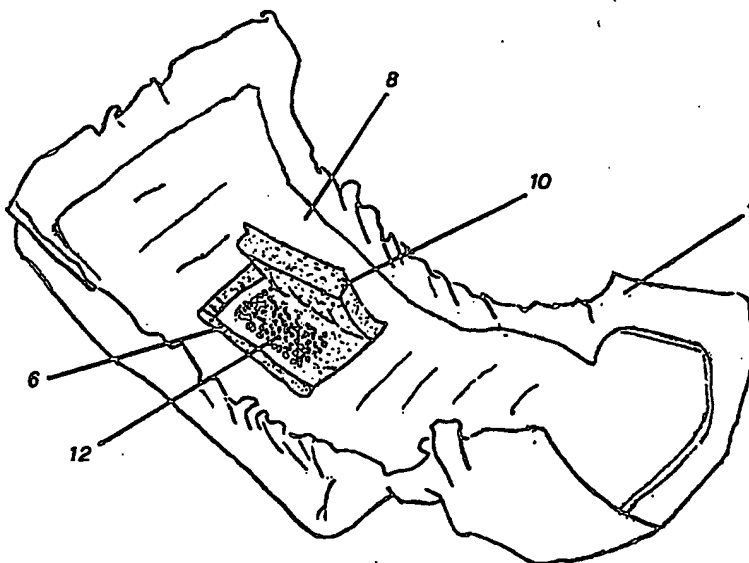
PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61L 15/46	A1	(11) International Publication Number: WO 95/19190 (43) International Publication Date: 20 July 1995 (20.07.95)
(21) International Application Number: PCT/IT94/00003 (22) International Filing Date: 17 January 1994 (17.01.94) (71)(72) Applicant and Inventor: GRAZIANI, Carlo, Alfredo [IT/IT]; Via Donizetti, 64, I-09128 Cagliari (IT). (74) Agent: SARPI, Maurizio; Studio Ferrario, Via Collina, 36, I-00187 Roma (IT).	(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>	

(54) Title: NAPKIN WITH BUFFER SUBSTANCE



(57) Abstract

A napkin for children and adults and/or a sanitary towel for ladies is disclosed to which a buffer substance is added to keep a physiologically correct pH on the surface of the skin for preventing the skin irritations due to the contact with faeces and urine. The buffer substances are placed within the fluff and/or on the surface of the napkin contacting the genitals of the user. Several buffer substances both of the organic and inorganic types as well as disinfectant buffer salts are indicated.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

DESCRIPTIONNapkin with buffer substanceTechnical field

The present invention relates to the field of the napkins for children and adults and/or sanitary towels for ladies, and more in particular concerns napkins and sanitary
05 towels to which a buffer substance is added to keep the surface of the skin at a pH which is physiologically correct, thus preventing the skin irritations.

Background art

10 The merits of the napkin as sanitary means are known for some time. It offers to the child the draining of urine and faeces without ruining his clothes and saves the parents the hard work of washing them continuously.

Furthermore, as the napkins are disposable items which
15 cannot then be recycled, they are free from any infection danger unlike the old triangular clothes which were not always duly disinfected.

However, besides such undoubted advantages napkins and sanitary towels also have a serious drawback. In fact, as
20 the faeces are absorbed, the change of the napkin by the parents is delayed, thus increasing the medium time of contact between faeces and skin. Such constant and prolonged contact with faeces characterized by a pH which is very different from that of the skin of the child
25 causes the maceration of the skin with reddening and ulceration of buttocks and genitals of the baby.

Disclosure of the invention

The invention seeks to obviate such drawback by providing a napkin capable of adjusting a correct pH, i.e. a pH corresponding to the physiological pH of the skin.

05 The inventive step at the base of the invention is that of adding to the napkins for children and adults as well as to the sanitary towels for ladies buffer substances both of the organic and inorganic types.

The invention is based on experimental data: the urine of
10 the first days has a clearly acid pH (pH 5,5) while the pH increases to 7 in the adult. Such data refers to the just excreted urine.

Ammonia is present in a considerable concentration both in the adult and in the child and represents about 5% of the
15 nitrogen in the just excreted urine. However, it increases after a short time from the miction due to the oxygen of the air which oxidizes urea to CO_2 and NH_3 . It should not even be excluded that the bacteria have a part in the increase of ammonia since they are in an ideal
20 environment: warm, wet and rich in nitrogenous excretions. Upon changing napkin the odour of ammonia can be usually smelled.

Under these conditions the napkins irritates the skin of the baby since the urine is highly alkaline.

25 It is known that the addition of buffer substances capable of neutralizing the acid and basic influences stabilizes the pH.

Generally the buffer substances are salts of polybasic acids or mixtures of weak acids (or bases) and their salts
30 formed of strong bases (or acids). The system is easy: the

concentration of hydrogen ions of a solution, i.e. the pH, can be changed by adding an acid or a base. If a buffer is added to the solution, the change (ΔpH) caused by adding an acid or a base is reduced.

05 The most common buffers which can be used are mentioned in the following list excluding for obvious reasons the buffer substances having non-physiological pH and those which would be used in a technically wrong way (for example liquid, volatile or toxic buffers):

10 Citric acid - sodium citrate buffer;
Monopotassic phosphate - bisodic phosphate buffer;
Tartaric acid - tartrate salt buffer;
Sorbic acid - sorbate salt buffer;
Benzoic acid - benzoate salt buffer.

15 Of course, acids or salts alone can also be used when the action thereof is physiologically compatible: for example, boric acid which is very weak. Furthermore, amphoteric substances such as metal hydroxides and/or aminoacids such as glycine.

20 Disinfectant buffer salts such as sorbates and benzoates alone or in addition to other buffers can also be used.

The "buffer capability" is given by the buffer value $T = 1/V \times dN/dpH$, where V is the volume of the solution in litres and N is the added amount of acid or base in
25 equivalents.

In the present case it is rather difficult to exactly calculate the buffer capability of the solution formed inside the napkin since the amount of solvent, i.e. the urine excreted by the baby, cannot be known even if the
30 amount of salts is known. It should be appreciated that

the number of mictions in a baby aged 12 months can be 2-6 to 15-20 per day. Such are the mean values as a lot of babies urinate 30-40 times a day. Generally in the second year of life the number of the mictions drops to 8-10 per day. The amount of urine after the first 2 or 3 days is more copious than in the adult in relation to the body surface and the weight. In spite of the variability of such values it is however possible to give an example for approximately calculating the buffer solution, thus providing significant information about the necessary buffer substances.

EXAMPLE 1

We assume that a baby aged two produces 600 cc of urine per day and that three napkin changes a day are provided (failing estimate). 600/3=200 cc of urine per napkin are provided.

In the hypothesis of using a phosphate buffer it is possible to calculate how many grams of sodium dihydrogenphosphate and sodium monohydrogenphosphate should be dissolved in 200 cc of solution to obtain a solution having a pH chosen at random, for example 6,40, and a buffer value also chosen at random, for example 0,05.

$$\begin{aligned} \text{Concentration} = C &= 0,05/23 \times (1+10^{\text{pKa}-\text{pH}})^2 / 10^{\text{pKa}-\text{pH}} = \\ &= 0,0217 \times (1+10^{0,81})^2 / 10^{0,81} = 0,0217 \times 55,6/6,456 = \\ &= 0,186 \text{ moles/l.} \end{aligned}$$

Additionally, indicating at T the buffer value and at W the fraction present as acid, $T = 2,3 \times C \times W \times (1-W)$.

After calculation:

$$W = 10^{\text{pKa}-\text{pH}} / 1 + 10^{\text{pKa}-\text{pH}},$$

i.e. in the present case:

$$W = 10^{0,81} / 1 + 10^{0,81} = 6,456 / 7,456 = 0,86.$$

Therefore:

$$C(\text{acid}) = \text{H}_2\text{PO}_4^- = W \times C = 0,86 \times 0,186 = 0,16 \text{ moles/l of acid}$$

$$C(\text{base}) = \text{HPO}_4^{2-} = (1-W) \times C = 0,14 \times 0,186 = 0,0026 \text{ moles/l of base.}$$

Finally, as the molar weights of NaH_2PO_4 and Na_2HPO_4 are 120 g/mole and 142 g/mole, respectively:

$$0,16 \times 120 = 19,2(\text{g/l}) \times 0,2 = 3,84 \text{ g of } \text{NaH}_2\text{PO}_4$$

$$0,026 \times 142 = 3,69 (\text{g/l}) \times 0,2 = 0,738 \text{ g of } \text{Na}_2\text{HPO}_4,$$

i.e. $3,84 + 0,738 = 4,578 \text{ g of powdered buffer phosphate}$ has to be introduced into a napkin.

In the sole accompanying drawing there is shown by way of a non-limitative example a preferred embodiment of the napkin according to the invention.

A napkin for babies is shown in a top perspective view. Such napkin generally indicated at 4 is provided with a window 6 in front of the genital area 8, i.e. the area contacting the genitals of the child, by scoring and raising the fluff 10. A buffer powder 12 is distributed in the fluff 10. In such embodiment the choice is fallen on a buffer powder consisting of citric acid-sodium citrate. The effectiveness of the invention has been proven directly in laboratory, after the napkin is closed, by depositing at the buffer zone of the napkin a liquid coat of a 1% phenolphthalein solution.

A 0,6% ammonia solution is poured to that zone. Initially a colour change to red of the phenolphthalein is provided.

After 5 minutes the red colour disappears due to the

buffer stabilizing the pH to the desired level, namely just acid.

If the problem of the urine is effectively solved by a depth buffer placed within the fluff as described above, 05 the problem of the faeces is conversely solved by placing a buffer at the surface, i.e. a buffer placed directly on the surface of the napkin so as to keep constant the pH of the skin before the excretion of the faeces. In this case, the buffer substance can preferably be chosen among creamy 10 or powdered substances allowing a buffer coat to be laid off on the surface of the napkin contacting the skin of the baby.

Claims

- 05 1. A napkin and/or sanitary towel for children and adults characterized in that there are incorporated buffer substances such as to keep the pH of the surface of the skin physiologically correct.
2. The napkin and/or sanitary towel for children and adults of the preceding claim characterized in that said buffer substances are placed within the fluff and/or on the surface of the napkin contacting the genitals of the user.
- 10 3. The napkin and/or sanitary towel for children and adults of the preceding claims characterized in that said buffer substances are salts of polybasic acids or mixtures of weak acids (or bases) with their salts formed of strong bases (or acids) both of the organic and inorganic type.
- 15 4. The napkin and/or sanitary towel for children and adults of the preceding claims characterized in that said buffer substances are in form of granules.
- 20 5. The napkin and/or sanitary towel for children and adults of the preceding claims characterized in that said buffer substances are in creamy or emulsified form.
- 25 6. The napkin and/or sanitary towel for children and adults of the preceding claims characterized in that a buffer powder consisting of citric acid-sodium citrate is

used as buffer substance.

7. The napkin and/or sanitary towel for children and adults of claims 1 to 5 characterized in that a buffer
05 formed of monopotassic phosphate-bisodic phosphate is used as buffer substance.

8. The napkin and/or sanitary towel for children and adults of claims 1 to 5 characterized in that a buffer
10 formed of tartaric acid-tartrate salt is used as buffer substance.

9. The napkin and/or sanitary towel for children and adults of claims 1 to 5 characterized in that buffer salts
15 having disinfectant action such as sorbates and benzoates alone or in addition to other buffers are used.

10. The napkin and/or sanitary towel for children and adults of claims 1 and 2 characterized in that an acid
20 and/or an extremely weak salt is used as buffer substance.

11. The napkin and/or sanitary towel for children and adults of claims 1 and 2 characterized in that an amphoteric substance is used as buffer substance.

25

12. The napkin and/or sanitary towel for children and adults of claims 1 and 2 characterized in that an aminoacid is used as buffer substance.

1/1

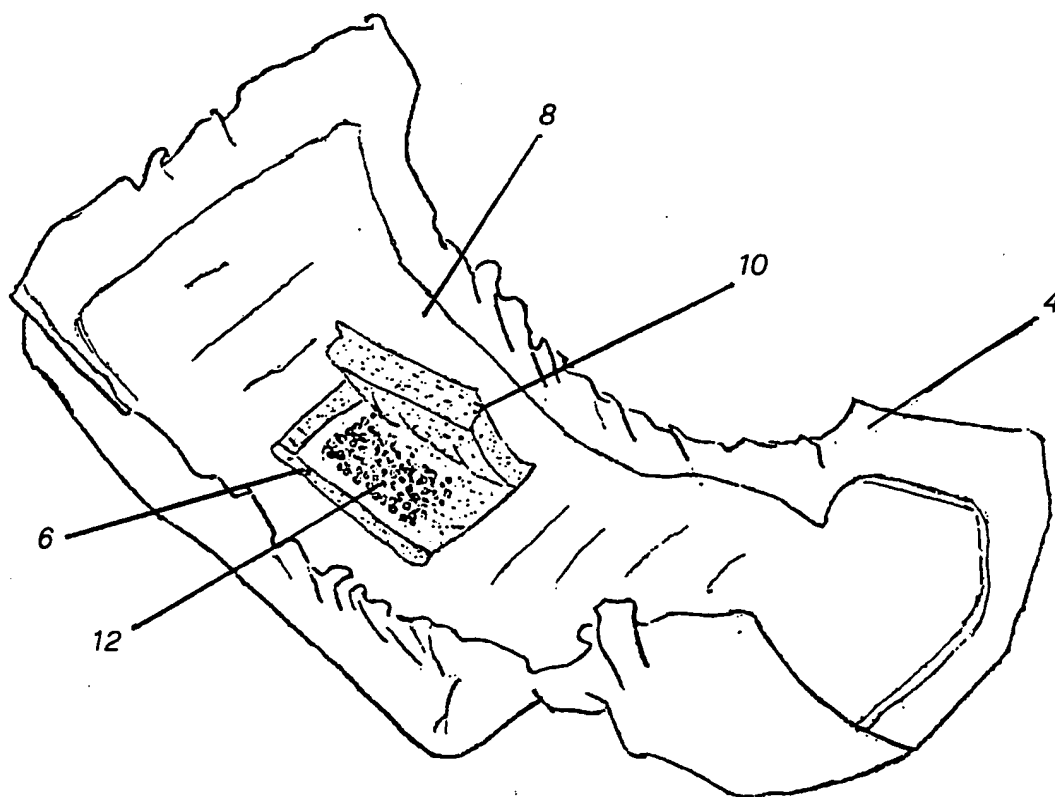


fig.1

INTERNATIONAL SEARCH REPORT

Intern al Application No
PCT/IT 94/00003A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L15/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP,A,0 564 307 (S. LEVI) 6 October 1993 see page 4, line 13 - line 31 see claims; examples ---	1-6,10 9,11,12
Y	DE,A,41 36 540 (AMERICAN ISRAELI PAPER MILLS LTD) 14 May 1992 see column 2, line 15 - line 40; claim 6 ---	9
Y	GB,A,1 517 043 (PERSONAL PRODUCTS CO.) 5 July 1978 see claims ---	11,12
X	GB,A,2 107 192 (UNIVERSITY OF DELAWARE) 27 April 1983 see page 1, line 116 - line 120; claim 6 --- -/--	9

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

17 August 1994

Date of mailing of the international search report

26.08.94

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Cousins-Van Steen, G

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IT 94/00003

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB,A,727 631 (AKTIEBOLAGET WALLCO) 6 April 1955 see claims; examples ----	1-5,8
X	EP,A,0 130 356 (HENKEL KOMMANDITGESELLSCHAFT AUF AKTIEN) 9 January 1985 see claims ---	6
X	BE,A,570 673 (M. KROLL) 15 September 1958 see claims -----	7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IT 94/00003

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0564307	06-10-93	AU-B- JP-A-	3553893 6056664	07-10-93 01-03-94

DE-A-4136540	14-05-92	NONE		

GB-A-1517043	05-07-78	US-A- CA-A- DE-A, C	3935862 1045544 2525847	03-02-76 02-01-79 02-01-76

GB-A-2107192	27-04-83	US-A- DE-A- FR-A- JP-A-	4431427 3236768 2513875 58075548	14-02-84 21-04-83 08-04-83 07-05-83

GB-A-727631		NONE		

EP-A-0130356	09-01-85	DE-A- JP-A-	3320218 60005149	06-12-84 11-01-85

BE-A-570673		NONE		
